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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,052	01/28/2002	Joseph M. Patti	P07069US04/BAS	3946

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/056,052	PATTI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12,16-26,32 and 37-45* is/are pending in the application.

4a) Of the above claim(s) *18,20-22,25 and 38-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,15-17,19,23,24,26,32 and 37* is/are rejected.

7)☒ Claim(s) *11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7-15-2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 1-7,9-12,16-26,32 and 37-45 are pending in the application. Claims 18, 20-22, and 25 are withdrawn as to non-elected inventions. In the prior action, mailed on August 27, 2003, claims 1-17, 19, 23, 24, and 26-37 were rejected. In the Response filed on February 27, 2004, the Applicant cancelled claims 8, 13, 14, 27-31, and 33-36; amended claims 1, 11, and 12; and added new claims 38-45. New claims 38-45 are withdrawn as to non-elected inventions. The Applicant elected a particular antibody in response to the restriction requirement. As no linking claim has been indicated as allowable, the claims drawn to other antibodies are withdrawn.

2. Claims 1-7, 9-12, 15-17, 19, 23, 24, 26. 32, and 37 are under consideration to the extent that they read on the elected invention.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on July 15, 2003 in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

4. It is noted that only pages 67-94 of the McCrae et al reference listed in the IDS have been provided. Thus, the reference has been considered only to the extent of the submitted pages.

5. The following reference is in a foreign language accompanied by an English abstract. Due to this, the reference has been examined only to the extent of the disclosure in the abstract.

WO 00/26671 (Reiter et al.)

Sequence Rules Compliance

6. **(Prior Objection- Withdrawn)** The nucleic acid encoding the variable light chain of the antibody 35-006 (pages 38-39) had not been amended such that it identifies the sequence by its Sequence Identifier. In view of the amendment of the specification, the objection is withdrawn.

Claim Objections

7. **(Prior Objection- Withdrawn)** Claim 1 was objected to because of the following informalities: the claim refers to the Staphylococcus aureus clumping factor A protein by its acronym (ClfA) without first identifying the protein by its complete name. In view of the amendment of the claim, the objection is withdrawn.

8. **(Prior Objection- Withdrawn)** Claim 8 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the cancellation of the claim, the objection is withdrawn.

9. **(Prior Objection- Withdrawn)** Claim 28 was objected to because of the following informalities: In view of the cancellation of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Withdrawn)** Claims 11-14, 27-31, and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

claims were rejected because the Applicant has not provided adequate written description for genera of antibodies that bind to the Clf33 sequence wherein the antibodies comprise the sequence of any of SEQ ID NOs: 25, 26, 28, or 29 (each representing a CDR from either the VH or VL chains). In view of the amendment or cancellation of each of these claims such that the rejected subject matter has been removed from the claims, the rejection is withdrawn.

12. **(Prior Rejection- Withdrawn)** Claims 11-14, 26-31, and 33-36 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an anti-ClfA antibody comprising the VH region of SEQ ID NO: 20, and the VL region of SEQ ID NO: 18, does not reasonably provide enablement for any anti-ClfA antibody comprising fewer than all of the CDRs of SEQ ID NOs: 25-29 as disclosed in the chains of SEQ ID NOs: 18 and 20. In view of the amendment or cancellation of each of these claims such that the rejected subject matter has been removed from the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. **(Prior Rejection- Maintained)** Claims 1-10, 15, 19, 23, 24, and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al., U.S. Patent 6,008,341. These claims read on monoclonal antibodies that bind to the ClfA protein, and more specifically, to

embodiments wherein the antibodies bind to the Clf33 region of the protein (comprising residues 221-550 of the ClfA protein). The teachings of Foster were also described in the prior action. Claim 8 has been cancelled from the application. The rejection of this claim is therefore withdrawn. The claims, and the teachings of the Foster patent have been described above. It is further noted that in addition to teaching the antibodies as useful for the treatment of S aureus infection, the reference also teaches their use in diagnostic assays for A. aureus.

The Applicant has traversed the rejection as it applies to the claims still under examination by arguing (in the form of a Declaration from Dr. Joseph Patti) that the claimed monoclonal antibodies had the unexpected result of being able to provide protection against S aureus infection. In support of this argument the Applicant first makes the argument that "it is in fact the case that even one skilled in the art cannot state with certainty which monoclonal antibodies will be successfully produced, much less provide protection against infection." Response, page 3. Dr Patti further states that "it has been very hard to predict with any certainty which monoclonal antibodies to which proteins, or fragments or domains, will result in antibodies capable of [affording] protection against infection." Declaration, paragraph 2. Thus, the Applicant appears to be arguing that the rejection should be withdrawn because there would be no reasonable expectation of success in the isolation of antibodies specific to Clf33 that would useful in passive immunization methods.

It is first noted that none of the rejected claims describe a specific antibody. Rather, each of the rejected claims reads on monoclonal antibodies against the ClfA protein or the Clf33 protein (a fragment of the ClfA protein) generally. Further, with the exception of claim 19, the claims also have no requirement that the claimed antibodies have a protective activity. Thus, it is

unclear how the arguments, which are directed to the production of antibodies with a protective capacity, are relevant to the rejection of claims 1-7, 9,10, 15, 23, 24, and 37. However, even if the argument was found persuasive with reference to these claims, the rejection would not be found persuasive in view of the further suggestion of the Foster reference that the antibodies may also be made for diagnostic purposes.

With respect to claim 19, the reference teaches that certain of the antibodies disclosed therein have the ability to inhibit bacterial adhesion to fibrinogen (e.g., col. 7), and that these antibodies may be used for the treatment of S aureus infection (col. 10, lines 63-67). While it is uncertain in any particular instance as to what antibodies may be achieved in making monoclonal antibodies, such is known in the art, and it is routine to screen for those antibodies with the desired specificity. See, e.g., U.S. Patent 5,240,833, column 7 lines 51-58; and U.S. Patent 5,326,696, column 1 lines 23-41. Thus, Foster provides sufficient information that those in the art would be able to screen for the antibodies indicated therein, and provides adequate teachings such that those in the art would have had a reasonable expectation of success in carrying out the invention.

In view of the above, the Applicant's arguments in traversal are not found persuasive. The rejection is therefore maintained over claims 1-7, 9,10, 15, 23, 24, and 37.

15. **(Prior Rejection-Maintained)** Claims 16 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Foster as applied to claim 1 above, and further in view of Na et al., Clin Diagn Lab Immunol 6(6): 924-29. Claims 16 and 17 are drawn to diagnostic kits comprising the claimed antibodies, and to kits wherein the antibodies are linked to a detectable label. The

Applicant has provided no further grounds of traversal other than those presented with respect to Foster above. The rejection is therefore maintained for the reasons indicated above.

16. **(Prior Rejection-Maintained)** Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foster as applied to claim 1 above, and further in view Sieradzki et al. (J Antimicrob Chemother 39 (Supp. A): 47-51). The Applicant has provided no further grounds of traversal other than those presented with respect to Foster above. The rejection is therefore maintained for the reasons indicated above.

17. **(Prior Rejection-Maintained)** Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foster as applied to claim 1 above, and further in view of the teachings of Hook et al. (U.S. Patent 6,288,214) and Emery et al. (U.S. 6,027,736). The Applicant has provided no further grounds of traversal other than those presented with respect to Foster above. The rejection is therefore maintained for the reasons indicated above.

Conclusion

18. No claims are allowed. Claims 11 and 12 are objected to as depending on rejected claims.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. The following prior art reference is made of record and is considered pertinent to applicant's disclosure. However, while relevant it is not used as a basis for rejection for the stated reasons.

> McDevitt et al., Molec Microbiol 18(5): 885-907 (of record in the July 2003 IDS). This reference teaches the binding of a region comprising residues 221-550 of the ClfA protein to fibrinogen. Pages 898-99. The reference also teaches that a protein consisting of this region was able to inhibit the fibrinogen binding neutralizing activity of antibodies, thereby indicating its ability to bind the antibodies. Page 899. However, the antibodies used in the reference are polyclonal in nature. See, page 11. Thus, the reference does not teach monoclonal antibodies as are described in the claims. The remaining teachings appear redundant to those of the Foster patent described above and in the prior action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 5/17/04
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